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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/642,531	08/15/2003	Elizabeth-France Marillia	3015-6072US	3187

24247 7590 04/21/2005

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EXAMINER

KOROMA, BARBA M

ART UNIT PAPER NUMBER

1638

DATE MAILED: 04/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/642,531

Applicant(s)

MARILLIA ET AL.

Examiner

Barba M. Koroma

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 8/15/03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: sequence data - SEQ ID No.1.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group SEQ ID No. 1, in the paper filed February 1, 2005, is hereby acknowledged. Claims 1-21 have been examined in this Office action.

Response to Traversal on Election of sequence

2. Applicant traversed the restriction requirement on election of sequence on the basis that the Commissioner for Patents has determined that up to 10 nucleotide sequences will be examined in a single application, and that it would not be an undue burden for the Office to examine four sequences. A further basis of traversal is that it would be undue burden on Applicant to file, prosecute, and pay for four separate applications in order to have SEQ ID Nos. 1-4 examined.

Applicant's arguments are not found persuasive because "up to ten nucleotides" includes one nucleotide sequence as required in the restriction election requirement, which meets the Commissioner's requirement.

The examiner maintains that the amount of machine, and personnel time, and the additional amount of physical resources required to prosecute more than one sequence, will make it burdensome to prosecute multiple sequences in a single application.

Since Applicant's ability to pay for patent applications is not a basis for restriction election, Applicant's argument in that regard is not considered. The restriction requirement is hereby maintained and made Final.

Objection to IDS

3. Information Disclosure Statement (IDS) is objected for failure to provide dates for some of the listed documents (See areas crossed out). Correction is requested.

Claim to Priority

4. If applicant desires benefit of a previously filed application under 35 U.S.C. 119e, specific reference to the earlier filed application must be made in the instant application. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. This should appear as the first sentence(s) of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. ____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be

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submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Claim Rejections 35 USC 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims, 1, 3-10, 12-15, and 17-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter which were not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention “requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials.” *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that “naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.” *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to “visualize or recognize the identity of the members of the genus.” *Id.*

See also MPEP Section 2163, page 156 of Chapter 2100 of the August 2001 version, column 2, bottom paragraph, where it is taught that:

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

See the Written Description Requirement Guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

The claims are broadly drawn to a genetically modified plant comprising a means for modulating mitochondrially generated acetyl-coA and/or respiration rate, and a process for modulating mitochondrially generated acetyl coA and/or respiration rate in a transgenic plant.

The specification describes nucleic acids encoding Brassica PDHK (of SEQ ID No. 1, 2, 3, and 4), and plants transformed therewith.

The specification does not describe other nucleic acids encoding Brassica PDHK or other nucleic acids that can be used to modulate mitochondrially generated acetyl coA and/or respiration rate in plants.

The specification fails to provide an adequate written description of the genus of nucleic acids, and therefore the claimed plants transformed therewith, are also inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing.

6. Claims 1, 3-10, 12-15, 17-20, are rejected are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID No. 1, does not reasonably provide enablement for other nucleic acids. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands*, 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists

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a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. The factors to be considered are as follows: Lack of guidance, State of the prior art, Nature of the invention, Unpredictability of the art, Quantity of experimentation necessary.

The claims are broadly drawn to a genetically transformed plant comprising a means for modulating mitochondrially generated acetyl-coA and/or respiration rate, where the said means is operably-linked to a promoter, a process for modulating mitochondrially-generated acetyl-coA comprising cloning a gene encoding Brassica pyruvate dehydrogenase kinase in the antisense orientation and transforming a plant with a vector.

The PDKH gene was cloned from *Brassica napus* (SEQ ID No.1) (example 1, page 9-10). The same approach was employed for cDNA cloning and sequence analysis of PDHK for *Brassica rapa* PDHK gene (SEQ ID No. 2) (example II, PAGE 10), *B. oleracea* (SEQ ID No. 3), *B. carinata* (SEQ ID No. 4) (example IV, page 11), *B. nigra*, *juncea*, *oleifera*, *balearica*, *cretica*, *elongate*, *tournefortii*, and *biennis* (examples V-VIII) (page 11). The specification teaches modulation of the oil content of multiple species of plants using anti-sense nucleic acid constructs of SEQ ID No. 1, 2, 3, or 4 (example IX, pages 11-12, bridging paragraph).

The specification does not provide guidance on other nucleic acids encoding Brassica PDHK or other nucleic acids that can be used to modulate mitochondrially generated acetyl coA and/or respiration rate in plants.

Lack of guidance: The specification does not teach how to modulate mitochondrially-generated acetyl-coA and/or respiration rate in a genetically transformed plant by transforming

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plants with any and all means operatively linked to a promoter; and the specification does not teach a combination of DNA fragments of SEQ ID Nos. 1-4.

State of the prior art: The method of modulating respiration using unidentified multiple heterologous sequences in a vector used to transform a plant for modulating mitochondrially generated acetyl-coA and/or respiration rate, is not taught in the prior art.

Nature of the invention: Since the alteration or enhancement of the metabolic function of a transformed plant cannot happen without following tangible method steps, including all necessary genes and proteins, one skilled in the art would not know how to make and use the plants encompassed by the broad claims.

Unpredictability of the art: Grof et al (Plant physiol. 1995. 108:1623-1629) teach that the catalytic activity of mitochondrial pyruvate dehydrogenase is variable during early development (page 1624, second paragraph). The variable nature of activity of pyruvate dehydrogenase kinase underscore the unpredictability of outcome in transformants.

Quantity of experimentation necessary: It would require numerous experimental approaches, undue trial and error, involving thousands of unidentified DNA sequences, and multiples of transformation events, to determine which nucleic acids would modulate mitochondrially-generated acetyl-coA and/or respiration rate as encompassed by the broad claims. In the absence of this information, one skilled in the art would not know how to make and use the invention as claimed. See Genentech, Inc. v. Novo Nordisk, A/S, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention. Given the breadth of the claims and

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the lack of guidance of the specification as discussed above, it would require undue experimentation to make and use the invention as claimed.

Claim Rejections 35 USC 101

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, and 10-14 of U.S. Patent Application No.

10222075. Although the conflicting claims are not identical, they are not patentably distinct from each other because SEQ ID No. 1 of the claimed invention has a 100% match with SEQ ID No. 1 of the cited reference (Application No. 10222075). The plants and processes encompassed in the instant claims are thus obvious over the claims of the copending application.

Claim Rejection 35 USC 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3-6, 8-10, 12-15, and 17-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Randall et al (US Patent No. 6265636. July 24, 2001).

The claims are broadly drawn to a means or a process for modulating mitochondrially-generated acetyl-coA and or respiration rate by transforming a plant with a gene encoding a Brassica pyruvate dehydrogenase kinase gene, or by transforming a plant including canola, with said means operatively linked to a promoter.

Randall et al teach methods and compositions relating to altering carbohydrate metabolism and or composition of plants. The invention provides isolated nucleic acids and their encoded proteins, expression cassettes, host cells, transgenic plants, and antibody compositions (See especially column 2, sections (a) and (b), lines 30-39). Randall et al teach transformation process (detailed description of invention, starting column 14)), ubiquitin promoter (column 26, lines 33-46), and several overlapping plants (claim 26, column 68).

This reference anticipates the instant invention by teaching an isolated nucleic acid that encodes pyruvate dehydrogenase kinase used to transform a plant, inherently modulating such metabolic activities as respiration rate.

9. Claims 1, 3, 5, 6, 8, 12, 14, 15, and 17-20, are rejected under 35 U.S.C. 102(e) as being anticipated by Zou et al (US Patent No. 6500670. Filing date February 9, 1998).

The claims are broadly drawn to genetically transformed plant comprising a means for modulating mitochondrially generated acetyl-coA and or respiration rate, said means operably-linked to a promoter; and the process of transforming a plant with a gene encoding a Brassica pyruvate dehydrogenase kinase.

Zou et al teach the isolation, purification, characterization and use of a mitochondrial pyruvate dehydrogenase kinase (PDHK) gene from the Brassicaceae. The invention includes isolated and purified DNA and relates to methods of regulating respiration rate amongst others in plants transformed with the gene (see abstract; claims 1-36 of columns 39-42; experimental procedures, columns 18-22). This reference anticipates instant invention by teaching an isolated nucleic acid from Arabidopsis (Brassica sp.) that encodes pyruvate dehydrogenase kinase used to transform a plant, thereby altering its metabolic activity, including respiration rate.

Conclusion

11. No claims are found allowable. SEQ ID No. 1 is deemed free of the prior art.

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Contact Information

12. Any inquiry concerning this or earlier communications from the Examiner should be directed to Barba M. Koroma, whose telephone number is 571-272-0899. The Examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at 571-272-0804. The fax phone numbers for the organization where this application or proceeding is assigned are 571 273 8300. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

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